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मानक

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Mazdoor Kisan Shakti Sangathan

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“पुराने को छोड़ नये के तरफ”

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“Step Out From the Old to the New”

IS 3237-4 (1986): Special Purpose Syringes, Part 4: Vaccine Syringe [MHD 12: Hospital Equipment]



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“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”



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## Indian Standard

SPECIFICATION FOR  
SPECIAL PURPOSE SYRINGES

## PART 4 VACCINE SYRINGE

**1. Scope** — Covers requirements for vaccine syringe for injecting viscous vaccine and serum.

**1.1** Unless otherwise stated in this standard the provisions covered in IS : 3235-1980 'General requirements for syringes for medical use ( *first revision* )' shall apply.

**2. Types, Shapes and Dimensions**

**2.1** The syringes shall be of the following two types:

*Type 1* Metal piston

*Type 2* All glass

**2.2** The typical shapes of the syringes are shown in Fig. 1 and 2.

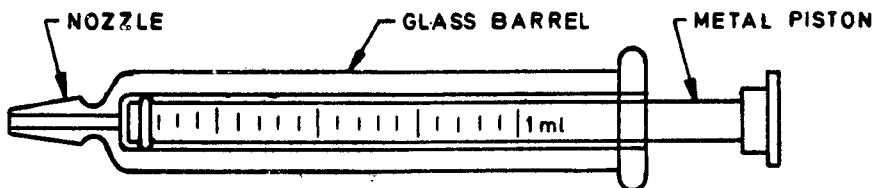


FIG. 1 VACCINE SYRINGE, METAL PISTON, TYPE 1, TYPICAL

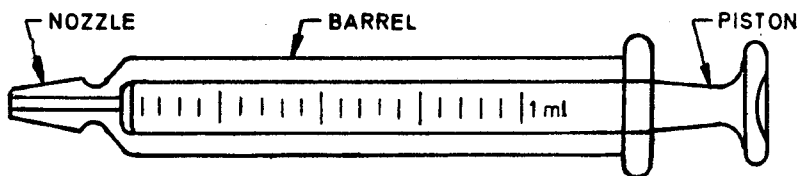


FIG. 2 VACCINE SYRINGE, ALL GLASS, TYPE 2, TYPICAL

**2.3** Scale intervals and other critical dimensions for the syringe shall be in accordance with Table 1.

**TABLE 1 CAPACITY AND CRITICAL DIMENSIONS OF VACCINE SYRINGE**

( *Clauses 2.3 and 3.2* )

	Type 1	Type 2
Graduated capacity	1 ml	1 ml
Tolerance on graduated capacity, percent	± 5	± 5
Maximum overall length	120 mm	85 mm
Minimum scale length	50 mm	26 mm
Scale intervals	0.05 ml	0.05 ml
Numbering of scale, units	5, 10, 15, 20	5, 10, 15, 20
Length of non-graduated part of barrel	30 mm, <i>Min</i>	25 mm, <i>Min</i>
Effluent diameter	1.2 to 1.8 mm	1.0 to 1.6 mm
Minimum thickness of glass	1.4 mm	1.2 mm

**3. Requirements**

3.1 Nozzle — The male conical tip of the nozzle shall be of Luer type and shall comply with IS : 3234 ( Part 1)-1986 'Specification for conical fittings with 8 percent (Luer) taper for syringes, needles and other medical equipment: Part 1 General requirements ( second revision )'.

3.2 Graduations and Numbering — The numbering of scale intervals shall be in accordance with Table 1. The number shall be close to but shall not touch the ends of graduation mark to which it relates.

3.3 Piston

3.3.1 Type 1 syringe shall have metal piston with silicon rubber head.

Type 2 syringe shall have ground glass piston.

3.3.2 The proximal end of piston shall be suitably shaped to form button with curve or flat surface to facilitate the thumb pressure.

3.4 The effluent shall be of adequate diameter and it shall be concentric with tip. The tip shall be properly ground to suit the hub of needle.

4, Tests -All tests as specified in 8 of IS : 3235-1980 shall apply.

**5. Marking**

5.1 Each syringe shall be legibly and indelibly marked with the following:

- a) Manufacturer's name, initials or recognized trade-mark; and
- b) Capacity and graduations as specified in Table 1, Fig. 1 and 2.

5.1.1 Certification marking — Details available with the Bureau of Indian Standards.

5.2 Each packet containing the syringe shall be marked with the type of the syringe in addition to the requirements as given in 5.1.

**8. Packing**

8.1 Each syringe shall be suitably housed in the cardboard box. Alternatively, the packing may be done as agreed to between the purchaser and the supplier.

7. Sampling -Sampling scheme and criteria for acceptance shall be as agreed to between the manufacturer and the purchaser. However, a recommended sampling plan is given in Appendix A.

**APPENDIX A**

( Clause 7 )

**SAMPLING PLAN AND CRITERIA FOR CONFORMITY**

**A-1. Let**

A-1.1 In any consignment, all the syringes produced from the same material of the same type, shape and dimension under similar conditions shall constitute a lot.

A-1.2 The number of syringes to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 2.

TABLE 2 SCALE OF SAMPLING

Lot Size (1)	Sample Size (2)	Sub-Sample Size (3)
up to 100	5	5
101 ,, 150	8	5
151 ,, 500	13	8
501 ,, 1000	20	13
1001 ,, 10000	32	13
10 001 ,, and above	50	20

**A-1.2.1** These syringes selected from the lot at random and in order to ensure the randomness of selection procedures given in IS : 4905-1988 'Methods for random sampling' may be followed.

## **A-2. Number of Tests and Criteria for Conformity**

**A-2.1** All the syringes selected at random in accordance with col 1 and 2 of Table 2 shall be tested for dimensions, capacity, shock test, leakage test, test for entrapped fluid and freedom from striae and strain. A syringe shall be considered as defective if it fails to meet any one or more of these requirements. A lot shall be considered as conforming to these requirements if none of the syringes in the sample is found to be defective in any of these tests.

**A-2.2** If the lot is found to be conforming to the requirements given in **A-2.1**, the test for corrosion, permanency of marking, dry heat test and alkalinity test shall be carried out on the sub-samples selected according to col 3 of Table 2. A lot shall be considered as conforming to these requirements if none of the syringes in the sub-sample fails to meet any of these requirements.

**A-2.3** The lot shall be considered as conforming to the standard if **A-2.1** and **A-2.2** are satisfied.

## **EXPLANATORY NOTE**

IS : 3237 was first published in 1965 and revised in 1980. It had then covered hypodermic syringes of small capacity, namely, insulin syringes, tuberculin syringes and BCG syringes. In the second revision of the standard undertaken in 1985, these special purpose syringes were covered in three separate parts. Subsequently, other special purpose syringes have also been added to this standard as its further parts as given below:

IS : 3237 (Part 1)-1985 Insulin syringes ( *second revision* )

IS : 3237 (Part 2)-1985 Tuberculin syringes ( *second revision* )

IS : 3237 (Part 3)-1985 BCG syringes ( *second revision* )

IS : 3237 (Part 5) 1986 Post operation care syringe

IS : 3237 (Part 6)-1986 Irrigation syringe

IS : 3237 (Part 7)-1986 Forced feeding syringe

IS : 3237 (Part 8)-1986 Angiography syringe.